UNITED STATES DISTRICT COURT

DISTRICT OF MAINE

ALELIA HILT,	)	
	)	
Plaintiff	)	
	)	
v.	)	Civil No. 99-132-B-H
	)	
JOHNSON & JOHNSON, INC., et al.,	)	
	)	
Defendants	)	

RECOMMENDED DECISION ON MOTION FOR PARTIAL SUMMARY JUDGMENT (DOCKET NO. 12)

During 1997-1999 many personal injury/products liability cases involving alleged allergic reactions caused by the use of and exposure to latex gloves were filed in the District of Maine. Eventually all of the District of Maine cases, plus hundreds of other cases, were transferred to the United States District Court for the Eastern District of Pennsylvania for coordinated or consolidated pretrial proceedings pursuant to 28 U.S.C. § 1407, the multi-district litigation panel's governing statute. On March 24, 2003, this case, along with numerous other cases, was remanded to the District of Maine and assigned to Judge D. Brock Hornby. On July 10, 2003, Judge Hornby entered a post-remand discovery order that divided the remanded cases into three distinct groupings. This case was placed in the third and final grouping and has proceeded through post-remand discovery in accordance with the scheduling order set for that group. On October 15, 2004, the Johnson & Johnson defendants (collectively "J&J") filed a motion for partial summary judgment (Docket No. 12) on the claims of misrepresentation and failure to warn brought by the plaintiff, Alelia Hilt, on two distinct grounds. J&J argues, first,

that Hilt cannot recover under any state law claim based on a failure to warn theory because such claims are subject to federal preemption and, second, that Hilt has not and cannot produce any evidence supporting a claim of fraudulent or negligent misrepresentation. I now recommend that the court **GRANT** the motion for partial summary judgment as to Count VI of the complaint, which sets forth the misrepresentation claims, and **DENY** the motion as to the portions of Count I, negligence, and Count II, strict products liability, that are premised on a failure to warn theory.

Undisputed Material Facts

The following facts are drawn from J&J's Local Rule 56 statement of material facts. (Docket No. 13.) Hilt did not file an opposing statement of facts. Simplifying matters even more is the fact that J&J actually filed a concise statement of material facts, reproduced here with minor edits and without including record citations.

From 1995 to 1999, Alelia Hill worked at Eastern Maine Medical Center (EMMC), as both a certified nurse assistant and a staff nurse. (Docket No. 13, ¶ 1.) Hilt claims that she used and was exposed to latex gloves at EMMC, including those manufactured or distributed by J&J. (Id., ¶ 2.) Hilt claims to have developed latex allergy due to her use of and/or exposure to latex gloves, including those manufactured or distributed by J&J. (Id., ¶ 3.) Hilt was never involved in purchasing latex gloves at EMMC. (Id., ¶ 4.) Hilt has no recollection of ever communicating with J&J, including any of J&J's employees or sales representatives, regarding latex gloves and/or latex allergy. (Id., ¶ 5.)

Discussion

Summary judgment is warranted only if "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c). The party moving for summary judgment must demonstrate an absence of evidence to support the nonmoving party's case. Celotex Corp. v. Catrett, 477 U.S. 317, 325 (1986). To determine whether this burden is met, the court must view the record in the light most favorable to the nonmoving party and give that party the benefit of all reasonable inferences in its favor. Nicolo v. Philip Morris, Inc., 201 F.3d 29, 33 (1st Cir. 2000). Once the moving party has made a preliminary showing that no genuine issue of material fact exists, the nonmovant must "produce specific facts, in suitable evidentiary form, to establish the presence of a trialworthy issue." Triangle Trading Co. v. Robroy Indus., Inc., 200 F.3d 1, 2 (1st Cir. 1999) (citation and internal punctuation omitted); Fed. R. Civ. P. 56(e). "As to any essential factual element of its claim on which the nonmovant would bear the burden of proof at trial, its failure to come forward with sufficient evidence to generate a trialworthy issue warrants summary judgment to the moving party." In re Spigel, 260 F.3d 27,31 (1st Cir. 2001) (citation and internal punctuation omitted).

1. The claims of fraudulent or negligent misrepresentation

Both sides agree the state law misrepresentation claims made by Hilt are claims based upon omitted information or silence, i.e., a failure to warn.[1] (Def. Mem. Of Law,

[1] There is absolutely no indication in the undisputed facts or the arguments of counsel that the misrepresentation claims in any way turn upon an argument that J&J failed to comply with federal labeling "guidelines," regulations, or statutory provisions under the Medical Device Amendments to the Food, Drug & Cosmetic Act or any other federal or state regulation or law. Thus, as I discuss below when addressing

Docket No. 15, at 8-9; Pl. Mem. Of Law, Docket No. 20, at 13-14.) J&J concedes that under Maine law the failure to disclose information may under certain circumstances rise to the level of either fraudulent or negligent misrepresentation. (Docket No. 15 at 8-9.) The argument that J&J presses in this motion for partial summary judgment is that Hilt has not and cannot produce any evidence establishing the elements of either claim. I address each theory in turn.

a. Fraudulent misrepresentation

To withstand the motion for partial summary judgment on her fraudulent misrepresentation claim, Hilt must demonstrate specific facts that create a dispute as to whether J&J (1) made a false representation (2) of a material fact, (3) with knowledge of its falsity or in reckless disregard of whether it was true or false (4) for the purpose of inducing plaintiff to act in reliance upon it, and (5) plaintiff justifiably relied upon the representation as true and acted upon it to her damage. Mariello v. Giguere, 667 A.2d 588, 590 (Me. 1995). If the matter were to proceed to trial, Hilt would have to prove each of those elements by clear and convincing evidence. Id.

As a general principle under Maine law, in the absence of a confidential or fiduciary relationship between the parties, it is not actionable fraud between buyers and sellers for the seller to remain silent regarding issues relating to economic matters. Barnes v. Zappia, 658 A.2d 1086, 1089 (Me. 1995). J&J relies exclusively on Barnes to maintain that Hilt cannot recover under a fraudulent misrepresentation claim because of the lack of a fiduciary relationship. I agree with J&J that there can be no recovery for fraudulent misrepresentation caused by silence, or a failure to warn, under the facts of

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the federal preemption argument, this is not a case wherein the omission of labeling information was contrary to FDA approved labeling requirements, suggestions, or guidelines.

this case because there is no allegation of a confidential or fiduciary relationship between Hilt and J&J.

I also note that, even if there were a fiduciary relationship, Hilt could not recover on a misrepresentation theory for pain and suffering and emotional injury. The Law Court has concluded that "pecuniary loss is an essential element of a fraud action and that damages for emotional or mental pain and suffering are not recoverable." Jourdain v. Dineen, 527 A.2d 1304, 1307 (Me. 1987); accord Veilleux v. NBC, 206 F.3d 92, 125 (1st Cir. 2000) ("Under Maine law, the proper measure of damages for a misrepresentation claim is plaintiff's lost bargain.") Thus, although the Restatement (Second) of Torts has a section discussing fraudulent misrepresentation that causes physical harm, see Restatement (Second) § 557A, the Maine Law Court has never specifically embraced that section of the Restatement and has, to the contrary, held that emotional damages are not available in the context of the misrepresentation torts. Jourdain, 527 A.2d at 1307 & n.2. Under Maine law, even if this case involved an active misrepresentation, full tort damage recovery would not be allowed.

b. Negligent misrepresentation

"Maine has adopted Section 552 of the Restatement (Second) of Torts as the appropriate standard for negligent misrepresentation claims." Bowers v. Allied Inv. Corp., 822 F. Supp. 835, 839 (D. Me.1993) (citing Diversified Foods, Inc. v. First Nat'l Bank of Boston, 605 A.2d 609, 615 (Me. 1992)). The Restatement (Second) provides:

> One who, in the course of his business, profession or employment, or in any other transaction in which he has a pecuniary interest, supplies false information, for the guidance of others in their business transactions, is subject to liability for pecuniary loss caused to them by their justifiable reliance upon the information if he fails to exercise reasonable care or competence in obtaining or communicating the information.

Restatement (Second) of Torts § 552(1) (1977). To avoid summary judgment in favor of J&J, Hilt would have to establish that J&J (1) in a transaction in which they had a pecuniary interest (2) supplied false information for the guidance of Hilt (3) without exercising reasonable care or competence and that (4) Hilt justifiably relied on that false information in her use of the latex gloves. Binette v. Dyer Library Ass'n., 688 A.2d 898, 903 (Me. 1996). The Maine Law Court has directly held that for purposes of negligent misrepresentation "silence rises to the level of supplying false information when such failure to disclose constitutes the breach of a statutory duty." Id. By the same token, the Law Court also noted that not every failure to disclose constitutes a misrepresentation. Id. In the present case Hilt does not point to any statutory duty to disclose any particular warning vis-à-vis the latex gloves at issue in this case. J&J's failure to warn regarding the latex gloves, even if negligent, is not actionable negligent misrepresentation under Maine law.

2. The failure to warn component of the negligence/products liability claim

J&J contends that Hilt is "barred from any remedies for all claims based on failure to warn . . . because these state common law claims are subject to federal preemption" under the Medical Device Amendments of 1976 (MDA), 21 U.S.C. §§ 360c – 360k. (Docket No. 15 at 2.) J&J argues that it would conflict with latex glove labeling requirements promulgated by the FDA if the court were to impose on J&J a duty to warn users of its latex gloves of a risk that the gloves might cause allergic reaction in some users. (Id. at 3-7.) J&J relies, primarily, on an order emanating from the Middle District of Pennsylvania, concerning a somewhat similar latex glove products liability suit, in

which the court held that the plaintiff's implied warranty claims were preempted by the MDA. (Id. at 4-5, citing Whitson v. Safeskin Corp., 313 F. Supp. 2d 473 (M.D. Pa. 2004)). Hilt argues that preemption under the MDA is not nearly as sweeping as J&J suggests and that her claims are not preempted based on the teachings of the lead Supreme Court case on MDA preemption, which, according to Hilt, the Whitson court failed to follow. (Docket No. 20 at 3-13, discussing Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996)). I conclude that Hilt is correct.

In 1996, the United States Supreme Court considered the extent to which preemption language in the MDA might impact common law products liability claims targeting medical devices subject to the Act. Lohr, 518 U.S. 470. As related by the Court, Congress passed the MDA in the 1970s in the face of growing consumer alarm over the safety and efficacy of certain medical devices, including intrauterine contraceptive devices, catheters, artificial heart valves, defibrillators, and pacemakers. Id. at 476. The MDA classifies medical devices in three categories based on the degree of risk presented to the public. Devices that do not present an unreasonable risk of illness or injury are designated Class I, subject to only minimal federal regulation by "general controls." 21 U.S.C. § 360c(a)(1)(A). At the other end of the spectrum are devices that either "present a potential unreasonable risk of illness or injury," or are "purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health." Id., § 360c(a)(1)(C). These devices are designated Class III devices and are subject to rigorous premarket approval (PMA) procedures. Lohr, 518 U.S. at 477. In between these two classes are Class II devices, which are subject to "special controls." 21 U.S.C. § 360c(a)(1)(B).

Latex gloves are Class I devices. In Lohr, the device under consideration was a pacemaker component, a Class III device. That distinction, however, has little significance to the present case because the device in Lohr was already on the market prior to the enactment of the MDA and therefore fell under certain exceptions provided by the MDA that prevented the device from being subjected to the heightened regulatory review (PMA process) normally imposed on a Class III device. Lohr, 518 at 477-78. Instead, the product was subjected to a § 510(k) review, or "premarket notification" process, that also applies to Class I and Class II devices. Id. at 478. The § 510(k) notification process is not comparable to the PMA process: "in contrast to the 1,200 hours necessary to complete a PMA review, the § 510(k) review is completed in an average of only 20 hours." Id. at 479. In short, the fact that latex gloves are Class I devices and that Class I devices are generally subjected to the least rigorous review does not necessarily mean that a products liability suit involving latex gloves is any less likely to be preempted by the MDA than a products liability suit involving a Class II or Class III device. Furthermore, the fact that latex gloves are Class I devices does not somehow make the reasoning of Lohr inapplicable to this case.

The plaintiff in Lohr was a recipient of an allegedly defective pacemaker component and sued Medtronic, the manufacturer, in Florida state court, alleging in support of a negligence theory that Medtronic breached its duty of care in several respects, including a failure to warn regarding the tendency of the pacemaker component to fail, and also alleging strict liability for placing on the market a defective device. Id. at 480-81. Medtronic removed the case to federal court and argued that both the negligence and the strict liability claims were preempted by 21 U.S.C. § 360k(a). Id. at 481. J&J

argues that the same section preempts the failure to warn component of Hilt's complaint. Section 360k(a) provides as follows:

> § 360k. State and local requirements respecting devices
> (a) General rule. Except as provided in subsection (b), no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement--
> (1) which is different from, or in addition to, any requirement applicable under this Act to the device, and
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a). The standard that this court must apply is found in Part V of Justice Stevens's opinion, which drew a majority of the Justices. The test of preemption devised there requires this court to look to whether "a particular state requirement threatens to interfere with a specific federal interest." Id. at 500. When considering the respective state requirement and federal interest, the court must look only to requirements and interests that are specific to the device in question, not to state requirements of "general applicability" (such as a damages award) or to federal interests that relate to an entire class of devices. Id. In doing so, the court must engage in "a careful comparison between the allegedly pre-empting federal requirement and the allegedly pre-empted state requirement to determine whether they fall within the intended pre-emptive scope of the statute and regulations." Id. at 500.[2]

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[2] The majority of the Justices relied heavily upon the FDA's own regulations regarding preemption under the MDA. Id. at 496-97 (Stevens, J., Part V majority); see also id. at 506-507 (Breyer, J., concurring). For the court's reference, I set forth the pertinent parts of the regulation here:

> (d) State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements. There are other State or local requirements that affect devices that are not preempted by section 521(a) of the act because they are not 'requirements applicable to a device' within the meaning of

It should be noted that the Supreme Court left for another day the question of whether a state common law claim might ever create a device-specific "requirement" that would be subject to preemption. Although all nine justices allowed that a case could arise in which a state court imposed a common law tort remedy that amounted to a "requirement" and triggered preemption under § 360k, the Justices voiced different levels of concern over the likelihood that § 360k might preempt a common law tort claim because of the nature of the remedy requested. Justice Stevens opined, in Part VI of his opinion, that it would "be rare indeed for a court hearing a common-law cause of action to issue a decree that has 'the effect of establishing a substantive requirement for a specific device.'" Lohr, 518 U.S. at 502-503. Justice Breyer, in his concurrence, and Justice O'Connor, in her opinion concurring in part and dissenting in part, expressed far greater concern about the number of circumstances in which state common law claims might be preempted. Thus, Justice Breyer did not join in Part VI, because he was "not convinced that future incidents of MDA pre-emption of common-law claims will be 'few'

> section 521(a) of the act. The following are examples of State or local requirements that are not regarded as preempted by section 521 of the act:
>
> (1) Section 521(a) does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (e.g., requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness)), or to unfair trade practices in which the requirements are not limited to devices.
>
> (2) Section 521(a) does not preempt State or local requirements that are equal to, or substantially identical to, requirements imposed by or under the act.
>
> * * * *
>
> (6)(i) Section 521(a) does not preempt State or local requirements respecting general enforcement, e.g., requirements that State inspection be permitted of factory records concerning all devices. . . . .
> (ii) Generally, section 521(a) does not preempt a State or local requirement prohibiting the manufacture of adulterated or misbranded devices. Where, however, such a prohibition has the effect of establishing a substantive requirement for a specific device, e.g., a specific labeling requirement, then the prohibition [may] be preempted.

21 C.F.R. § 808.1(d) (1995).

or 'rare.'" Id. at 508 (discussing a hypothetical case). Similarly, Justice O'Connor reasoned that even the imposition of state common law damages would amount to a "requirement" and, thus, § 360k preemption of common law claims would be appropriate in a greater number of circumstances. Id. at 512-13. At least one court, the Tenth Circuit Court of Appeals, appears to hold that common law tort claims are never preempted under the rule established in Lohr because they are "predicated upon a general duty applicable to every manufacturer to inform users and purchasers of potentially dangerous items of the risks involved in the use," and, therefore, cannot be viewed as device-specific requirements "that would threaten the MDA's federal interests." Oja v. Howmedica, Inc., 111 F.3d 782, 789 (10th Cir. 1997) (internal quotation marks and citation omitted). This position appears to be a viable one because the Supreme Court's holding in Lohr was, essentially, that there was no pacemaker-specific federal requirement with which a common law remedy could conflict. See 518 U.S. at 494 (discussing design claim and the absence of a federal design requirement), 498-99 (discussing manufacturing and labeling claim and the absence of specific federal requirements).[3]

Making sense of Lohr is key to determining whether or not a state common law claim has been preempted.[4] The Eighth Circuit, in a case finding that a failure to warn

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[3] Justice Stevens did offer as an additional rationale that "state common-law requirements" are not "specifically developed 'with respect to' medical devices" and that "the general duty to inform users and purchasers of potentially dangerous items of the risks involved in their use . . . [is not] a threat to federal requirements." Lohr, 518 U.S. at 501. However, it is not clear to me that Justice Breyer's concurrence can be harmonized with this aspect of Justice Stevens's opinion. See id. 518 U.S. at 504-505 (presenting Justice Breyer's "1-inch wire" hypothetical, which demonstrates how rulings on common law products liability claims might well impose device specific state "requirements").

[4] The leading First Circuit case on MDA preemption issues is King v. Collagen Corporation, 983 F.2d 1130 (1st Cir. 1993). At least one judge in this circuit has concluded that the majority opinion's statement of the law in Lohr directly opposes the First Circuit's legal basis for its holding in King. See Haidak v. Collagen Corp., 67 F. Supp. 2d 21 (D. Mass. 1999).

claim in a product liability case against a bone cement manufacturer was preempted, described the inquiry thusly:

> The crux of the disagreement in Lohr between the Stevens majority and the dissenters is the meaning to be given to the statutory phrase "a requirement different from, or in addition to." Lohr instructs that state requirements--including common law duties--are preempted to the extent that they interfere with specific federal requirements. The state and federal restrictions must be "carefully compar[ed]" to ascertain whether there is interference between them--that being the "overarching concern" of the test articulated by Justice Stevens and joined in by Justice Breyer. Id. at 500, 116 S.Ct. 2240. A state claim will be preempted in circumstances where "a particular state requirement threatens to interfere with a specific federal interest." Id. In his concurring opinion Justice Breyer phrased the issue as whether an "actual conflict" exists between the state and federal requirements, id. at 508, 116 S.Ct. 2240, and that opinion deserves close attention since his vote created the majority. The key question before the court is whether the specific state requirement [the plaintiff] wishes to impose on [the defendant] would interfere with a specific federal requirement, but the question may also be phrased as whether the specific state and federal requirements conflict.

Brooks v. Howmedica, Inc., 273 F.3d 785, 794 (8th Cir. 2001) (footnote omitted). The Eighth Circuit thus places special emphasis on Justice Breyer's concurring opinion. The key points made by Justice Breyer are that a court should (1) look to whether the FDA has communicated an intent to preempt the imposition of requirements on a device, such as "through statements in 'regulations, preambles, interpretive statements, and responses to comments,'" Lohr, 518 U.S. at 506 (Breyer, J., concurring) and (2) not lose sight of "ordinary principles" of preemption, which coach that preemption occurs when, among other factors, "compliance with both [state and federal requirements] is impossible or . . . the state requirement 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress,'" Id. at 507 (Breyer, J., concurring).

In the present case J&J does not claim that a specific federal statute or regulation regarding labeling preempts the failure to warn component of Hilt's common law claims.

Nor does J&J claim that latex gloves have been subjected to regulatory scrutiny concerning the risk of allergic reaction to users of latex gloves or the need for specific warnings on latex glove boxes. Instead, they rely upon a 1993 FDA publication entitled "Regulatory Requirements for Medical Gloves—A Workshop Manual" (the Glove Manual). According to Justice Breyer, a document of this kind, although not necessarily rising to the level of a formal FDA "regulation," is nevertheless relevant to the preemption inquiry. Lohr, 518 U.S. at 506 (Breyer, J., concurring). J&J introduces the Glove Manual as an attachment to its memorandum of law (Docket No. 15) and does not introduce the document or any of its provisions in the body of its statement of material facts (Docket No. 13). That may not be appropriate practice in this District, but Hilt has raised no objection, leading me to take notice of the document and its contents.

At least one federal district court has concluded that through the Glove Manual the FDA "established specific labeling requirements for latex gloves." Whitson v. Safeskin Corp., 313 F.Supp.2d 473 (M.D. Pa. 2004) (granting summary judgment to latex glove manufacturer against plaintiff's claim for breach of implied warranty).[5] The Whitson court's description of the Glove Manual is accurate as far as it goes, and if the court were able to apply the far easier test espoused by the dissenters in Lohr, it would be fairly easy to conclude that Hilt's failure to warn claim amounts to an attempt to establish a state-imposed labeling requirement that is in addition to the federal requirement. However, my conclusion is that the labeling requirements set forth in the Glove Manual

[5] It is worth noting that Whitson, although a latex glove case, was not a failure to warn case. The issue raised by that case related to claims for breach of implied warranties of fitness and merchantability. The court's alternative holding, in the event the implied warranty claims were not preempted by the MDA, was that the claims failed under Pennsylvania implied warranty law in any event because the "ordinary purpose" of latex gloves is "to protect the wearer from transmitting, or gaining exposure to, blood-borne illness" and plaintiff's claim was the gloves caused her latex allergy. Whitson, 313 F. Supp. 2d at 480.

do not amount to a federal requirement concerning warnings about allergic reactions to latex and, therefore, cannot preempt Hilt's failure to warn claims.

The FDA labeling requirements, as represented in the Glove Manual, deal with specific issues including the name and place of business of the manufacturer, packer, or distributor, the identity of the product, the quantity of the product, the country of origin, if applicable, a statement of latex identification (e.g., "natural rubber latex"), and the expiration date. (Glove Manual, at 3-2 & 3-3.) Beginning at page 3-5, the Glove Manual also contains the following information concerning "additional labeling claims," which is to be distinguished from the "required examination glove labeling" information that begins at page 3-2:

> **Hypoallergenicity**
>
> FDA has reviewed its 510(k) policy for medical gloves containing label claims of hypoallergenicity. FDA is planning to require removal of hypoallergenic claims from gloves that had received prior 510(k) marketing clearance.
>
> The term "hypoallergenic" does not have a uniform and well-defined meaning among medical glove manufacturers. A medical glove may state in its labeling that the product is "hypoallergenic," is "safer for sensitive skin," or may contain other phrases that imply that there will be significantly less adverse skin reactions. The manufacturer must document by scientific studies that these claims are not false or misleading.

(Glove Manual, at 3-6.) It is apparent from a reading of this portion of the Glove Manual that the purpose of this provision is to prevent manufacturers from unilaterally adding hypoallergenicity claims to labels placed on latex gloves that had previously receive 510(k) clearance and to require those manufacturers wishing to make such claims to go through a new 510(k) process and substantiate such claims. Although this section of the Glove Manual, dealing as it does with hypoallergenicity claims, apparently has nothing to

do with the type of latex gloves at issue in this case, since it is not highlighted by either party in their memoranda, it does reveal something about the state of labeling requirements and FDA regulations as of 1993. It is apparent that the FDA did not have comprehensive labeling requirements vis-à-vis allergic reactions in place at the time of the publication of the Glove Manual. In fact, the Glove Manual tells us that "[a] medical glove may state in its labeling that the product is 'hypoallergenic,' is 'safer for sensitive skin,' or *may contain other phrases that imply that there will be significantly less adverse skin reactions.*" (Id. at 3-6 (emphasis added).) That information suggests to me that there was no specific federal regulation regarding the labeling of latex gloves vis-à-vis allergic reactions at the time the Glove Manual was prepared and, therefore, there is no basis to determine that the court's possible imposition on J&J of a duty to warn of the risk of allergic reactions would amount to a "requirement" that is "different from, or in addition to, the applicable federal requirements." 21 U.S.C. §360k(a).

Thus, if one attempts to perform a Lohr analysis of whether Hilt's state law claim for failure to warn might conflict with federal regulations, this record leaves one with a complete lack of evidence. First, as already discussed, there is no federal warning requirement to consider. Second, the record on this summary judgment motion does not even reveal what warning Hilt would urge that the court adopt as necessary in order to adequately warn of the dangers of latex gloves vis-à-vis allergic reactions. For instance, if a "warnings expert" were to opine that listing the common identity name ("latex glove") on the label was insufficient and that the manufacturer should have included a more scientific identity label (such as naming specific proteins contained in the latex), there would be a clear conflict between an FDA requirement and the state requirement

sought to be imposed. That such a warning would be an addition to the "statement of identity" or "latex identification" requirements set forth in the Glove Manual is obvious. However, adopting Justice Breyer's analysis, it is not nearly so obvious that an as yet unidentified proposed warning regarding the risk of allergic reaction would conflict with the federal interests that are represented by the Glove Manual. Indeed, the Glove Manual seems to suggest that as of 1993 the FDA allowed labeling claims of "hypoallergenic" for certain gloves. How would a warning label such as "non-hypoallergenic" or "may cause allergies" conflict with any federal interest represented by the Glove Manual or be in addition to or different from the Glove Manual? Of course, we do not have the factual basis of the failure to warn claim before the court, and attempts to posit exactly what the failure to warn claim might be about are simply speculation.

The Lohr analysis is not concerned with placing extra safety burdens on manufacturers, so long as those burdens do not run afoul of a federal interest. In a case such as this one, involving a Class I device subject to minimal federal regulation, if J&J is claiming that the failure to warn component of the negligence and product liability claims runs afoul of federal regulations, it has an obligation to develop that argument with some specificity. Since we do not know what labeling requirement Hilt maintains should be incorporated and we don't know what labeling requirements vis-à-vis allergic reactions the FDA actually requires, it is virtually impossible on this record to make the preemption analysis that Lohr and the FDA's own preemption regulation require. Under 21 C.F.R. § 808.1(d) a state requirement is preempted only when the Food and Drug Administration has established specific counterpart requirements applicable to the device under the MDA. (See, supra, note 2.) That regulation coupled with the Lohr decision

leads me to conclude that before the court could find that Hilt's common law claims are preempted it would first need to examine what it is that the claim would require the label to contain and then examine what relevant labeling requirements exist with specificity vis-à-vis the device. On this summary judgment record, where the court is presented with nothing more that a generic complaint alleging failure to warn and a Glove Manual that contains no definitive regulations regarding allergic reactions and gloves, I cannot conclude that these common law claims are preempted.

Conclusion

Based upon the foregoing, I now **RECOMMEND** that the court **GRANT** the motion for partial summary judgment as to Count VI of the complaint, alleging misrepresentation, and **DENY** the motion as to failure to warn claims included in Count I (negligence) and Count II (strict products liability) of the complaint.

NOTICE

> A party may file objections to those specified portions of a magistrate judge's report or proposed findings or recommended decisions entered pursuant to 28 U.S.C. § 636(b)(1)(B) for which *de novo* review by the district court is sought, together with a supporting memorandum, and request for oral argument before the district judge, if any is sought, within ten (10) days of being served with a copy thereof. A responsive memorandum and any request for oral argument before the district judge shall be filed within ten (10) days after the filing of the objection.
>
> Failure to file a timely objection shall constitute a waiver of the right to *de novo* review by the district court and to appeal the district court's order.

/s/ Margaret J. Kravchuk
U.S. Magistrate Judge

Dated January 7, 2005

HILT v. JOHNSON & JOHNSON, et al
Assigned to: JUDGE D. BROCK HORNBY
Demand: $0

Cause: 28:1332 Diversity-Personal Injury

Date Filed: 05/20/1999
Jury Demand: Plaintiff
Nature of Suit: 365 Personal Inj. Prod. Liability
Jurisdiction: Diversity

Plaintiff

ALELIA HILT represented by **JOHN R. TROTMAN, JR.**
MONHEIT, MONHEIT, SILVERMAN & FODERA
ELEVEN PENN CENTER
1835 MARKET STREET
ELEVEN PENN CTR STE 2600
PHILADELPHIA, PA 19103
(215) 561-2100
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

JON HADDOW
FARRELL, ROSENBLATT & RUSSELL
P.O. BOX 738
BANGOR, ME 4402-738
(207) 990-3314
Email: jah@frrlegal.com
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

V.

Defendant

JOHNSON & JOHNSON, INC represented by **BARBARA L. GOODWIN**
MURRAY, PLUMB & MURRAY
PO BOX 9785
PORTLAND, ME 04101-5085
207-773-5651
Email: bgoodwin@mpmlaw.com
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

DAVID B. SUDZUS
KELLEY, DRYE & WARREN, LLP

333 WEST WACKER DRIVE
SUITE 2600
CHICAGO, IL 60606
312/857-7070
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

THOMAS C. NEWMAN
MURRAY, PLUMB & MURRAY
PO BOX 9785
PORTLAND, ME 04101-5085
773-5651
Email: tnewman@mpmlaw.com
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

JOHN DAMES
KELLEY, DRYE & WARREN, LLP
333 WEST WACKER DRIVE
SUITE 2600
CHICAGO, IL 60606
312/857-7070
ATTORNEY TO BE NOTICED

LARA C. OTSUKA
KELLEY, DRYE & WARREN, LLP
333 WEST WACKER DRIVE
SUITE 2600
CHICAGO, IL 60606
312-857-7070
ATTORNEY TO BE NOTICED

Defendant

JOHNSON & JOHNSON MEDICAL represented by **BARBARA L. GOODWIN**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

DAVID B. SUDZUS
(See above for address)
LEAD ATTORNEY

ATTORNEY TO BE NOTICED

THOMAS C. NEWMAN
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

JOHN DAMES
(See above for address)
ATTORNEY TO BE NOTICED

LARA C. OTSUKA
(See above for address)
ATTORNEY TO BE NOTICED

Defendant

JOHNSON & JOHNSON MEDICAL MANUFACTURING, SDN. BHD

represented by **BARBARA L. GOODWIN**
(See above for address)
ATTORNEY TO BE NOTICED

THOMAS C. NEWMAN
(See above for address)

Defendant

JOHNSON & JOHNSON HEALTH CARE SYSTEMS, INC.

represented by **BARBARA L. GOODWIN**
(See above for address)
ATTORNEY TO BE NOTICED

THOMAS C. NEWMAN
(See above for address)

Defendant

ETHICON, INC

represented by **BARBARA L. GOODWIN**
(See above for address)
ATTORNEY TO BE NOTICED

THOMAS C. NEWMAN
(See above for address)

Defendant

JOHN DOES 1-100